K103800

JAN 2 6 2011

510(K) STATEMENT / SUMMARY
AS REQUIRED BY SECTION 807.92(c)

Braun Thermoscan® IRT 4000 Series/Pro 4000 Series Infra-Red Ear Thermometers with Probe Cover

1. SUBMITTED BY:

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2. DATE OF SUMMARY PREPARATION: December 22, 2010

3. DEVICE NAME AND PREDICATE DEVICES:

	Device	Accessory
Proprietary Name	Braun Thermoscan® Pro 4000 Series/IRT 4000 Series Thermometers	Probe Cover
Common/Usual Name	Infra Red Ear Thermometer	Probe Cover
Classification Name	Clinical Electronic Thermometer	Probe over

Table 1: Device and Accessory Names

PREDICATE DEVICES:
1. Braun Thermoscan® IRT4000/PRO 4000 Series Thermometer – K031928/101747
2. Braun Thermoscan® IRT3000 Series Thermometer – K983295

4. DEVICE CLASSIFICATION:

Clinical Electronic Thermometer (21CFR 880.2910 Product Code FFL) has been classified under section 513 of the Act as Class II by the General Hospital Devices Panel.

5. DEVICE DESCRIPTION:

IRT/Pro 4000 Series Thermometer:
The Braun Thermoscan® Pro/IRT 4000 series thermometer is a hand held instrument (thermometer) that measures human body temperature through the opening of the auditory canal. It is a single mode ear thermometer that measures the natural thermal infrared radiation emitted from the tympanic membrane and adjacent surfaces with a built-in correction

algorithm to compensate the influence of ambient temperature using a heated tip. The difference between the Pro 4000 series thermometer and the IRT 4000 series thermometer is that the Pro 4000 series thermometer is meant for professional use in hospitals and healthcare or professional office settings, while the IRT 4000 series is meant for home use. The thermometer uses a probe cover that is used as a sanitary barrier between the infra red thermometer and the ear canal to prevent any ear secretions or particulates from being transferred between different people.

This submission supports a change in the manufacturing site for the IRT/Pro 4000 series thermometer from Braun in Walldurn, Germany to Keytronics in Juarez, Mexico.

6. DEVICE TECHNOLOGICAL CHARACTERISTICS

The IRT/Pro 4000 Series thermometer is an ear thermometer that makes a temperature determination based on the infrared radiation emitted by the tympanic membrane in the ear. This thermometer also warms the probe tip to a temperature close to the normal body temperature, which is the key to getting the high clinical accuracy and repeatability that is characteristic of this device.

There are two major goals of operating with a warmed-up probe tip:

- First is the reduction of the so called blackbody effect (due to the difference between the ambient room temperature and the human body temperature).
- The second goal is to increase the repeatability of measurement results in application to the human auditory canal.

Both of these address the limitations of Infrared ear thermometers commonly used in taking ear measurements making the IRT/Pro 4000 series thermometer a very accurate and repeatable thermometer.

For the measurement of the target human body core temperature, the thermometer has two sensors integrated in a single housing that resides in the probe tip or speculum of the thermometer. The thermopile sensor is the *key sensor that measures the infrared radiation emitted by the tympanic membrane* in the ear and the other sensor measures the sensor temperature due to the warming of the probe tip. The warming of the probe tip is monitored through a safety circuit that ensures that the tip is not warmed beyond the predetermined limit.

In addition the thermometer has a third sensor within the body that measures the ambient temperature which is integral to the algorithm used to do the temperature determination.

The sensors convert the signal to an electric voltage signal which is then subjected to signal conditioning and then fed to the microprocessor. The microprocessor uses a proprietary algorithm that processes the signals and adjusts them to take into account errors due to

- positional feedback,
- temperature gradients and
- clinical offsets.

The algorithm compensates for these three kinds of errors and using the calibration parameters obtained from the calibration of the thermometer gives a target temperature determination value which is then displayed on the thermometer display.

Therefore, the key technological characteristics for this thermometer include the sensing, the signal conditioning, and algorithmic computation based on the compensation of various errors due to positional feedback, temperature gradients and clinical offsets.

None of the hardware, main operating principle, algorithm or device software has changed as part of this change. This change only involves a relocation of the manufacturing facility and the associated minor changes related to the manufacturing process and alternate vendors.

7. STATEMENT OF INTENDED USE / INDICATIONS FOR USE:

The Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometers is indicated for the intermittent measurement and monitoring of human body temperature by consumers of all ages in a home use/professional use environment. The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal.

8. SUMMARY OF VERIFICATION ACTIVITIES

In order to show that the IRT/Pro 4000 Series thermometers manufactured at the new manufacturing site (in Juarez, Mexico) that used the validated process are equivalent to the current thermometers manufactured at Walldurn (Germany), verification activities were carried out to show that the thermometers manufactured using the newly validated process were statistically equivalent to the thermometers currently produced (also referred to as the "gold standard samples"). This statistical analysis was carried out by an independent statistical contractor independent from Kaz. In addition process validation for the manufacturing site change comprising installation qualification, operational qualification and performance qualification in accordance with the Global Harmonization Task Force methodology on process validation was successfully completed.

Test Methods

A. To show statistical equivalency, the Black welder method for showing statistical equivalency was used. Readings were taken using the gold samples (old units made in Walldurn) to get a sample bias using the blackbody as a reference. This was repeated for 5 different combinations of temperature and humidity (5E test criteria per ASTM 1965) Readings were then taken using the new thermometers manufactured in Juarez, Mexico and the sample bias was calculated using the black body as a reference for the same 5E test conditions. A difference in bias and standard deviation between the readings was then calculated for each of these data points between the old and the new thermometers. Using a delta that is 10% of the specification range and a standard deviation based on historical data, a sample size of 42 (total of 84 comprising 42 each of the old and new devices) was estimated to show equivalence.

B. Biocompatibility Testing: Since the materials in contact with the human body were identical or equivalent between the old and the new devices, no biocompatibility testing was required.

C. Safety and EMC Testing: Since there was no change to the product circuit or specifications, no safety or EMC testing was necessary.

Acceptance Criteria:

A. A tolerance (delta) of $\pm$ 0.04 (20% of the tolerance or range of 0.2 deg C) as required by the Blackwelder method was deemed adequate to show equivalency between the two data set populations. If the 95% confidence intervals for the difference between the two dataset populations were within these acceptance criteria, the two sets of data can be considered to be equivalent.

B. Process Validation: Acceptance Criteria were as defined in the process validation (IQ, OQ, PQ) Protocols.

Statistical Analysis

A. For the gold standard samples as well as for the new probe covers made at the new site, ninety five (95) % and ninety (90%) confidence intervals were calculated for the difference between the biases and standard deviation for the two data set populations between the thermometers at the current site and the new site. Since these 95% and 90%confidence intervals were within the chosen acceptance criteria of $\pm$0.04 deg F, the acceptance criteria were met and therefore the data provided evidence of process and device equivalence between current and new thermometers in terms of their reading accuracy.

B. The IQ, OQ and PQ implementation met the acceptance criteria listed in the protocols.

Conclusion

Based on these results, we can conclude that the thermometers made using the new process set up at the new manufacturing site will not affect the temperature measurements taken by the thermometer.

9. SUBSTANTIAL EQUIVALENCE:

There is no change to the intended use, indications for use, product specifications or technology or operating principle of the Braun Thermoscan® PRO 4000 series and Braun Thermoscan® IRT 4000 series Clinical Infrared Ear Thermometers or that of the probe covers (K031928/K101747).

The manufacturing site for the IRT/Pro 4000 series thermometer has changed from Braun Walldurn in Germany to Keytronics EMS in Juarez Mexico. There was no change to the manufacturing site for the probe covers that is being submitted as part of this submission.

A process validation of the operation at the new manufacturing site showed that there are no new questions of safety and effectiveness when compared to the predicate device (IRT/Pro 4000 series thermometer described in K031928/K101747). There is no change to the product and the manufacturing site transfer was carried out successfully through process validation and device equivalency testing. Hence the new thermometer manufactured at the new site is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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JAN 26 2011

Re: K103800
Trade/Device Name: Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 12, 2011
Received: January 18, 2011

Dear Mr. Kasbekar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

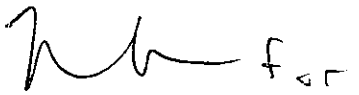
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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Enclosure

Indications for Use

510(k) Number (if known): K103800 ~~not yet assigned~~

Device Name: *Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometer*

Indications For Use:

The Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometers is indicated for the intermittent measurement and monitoring of human body temperature by consumers of all ages in a home use/professional use environment respectively.

The probe cover is used as a sanitary barrier between the infra-red thermometer and the ear canal.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

1/26/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103800